# CAREALL DIPHENHYDRAMINE- diphenhydramine hydrochloride tablet, coated New World Imports, Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

-----

## **Drug Facts**

#### **Active Ingredient**

Diphenhydramine HCl 25mg

### Purpose

Antihistamine

#### Keep out of reach of children

In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) immediately.

#### Uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

Sneezing, runny nose, itchy / watery eyes, and itching of the nose or throat

Temporarily relieves these symptoms associated with the common cold:

Sneezing, runny nose

#### Warnings

Do not use with any other products containing diphenhydramine, including ones used on skin

#### Ask a doctor before use if you have:

A breathing problem such as emphysema or chronic bronchitis

Glaucoma

Trouble urinating due to an enlarged prostate gland

**Ask a doctor or pharmacist before use if you** are taking sedatives or tranquilizers

#### When using this product:

Marked drowsiness may occur

Avoid alcoholic beverages

Alcohol, sedatives, and tranquilizers may increase drowsiness

Be careful when driving a motor vehicle or operating machinery

Excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use

#### Directions

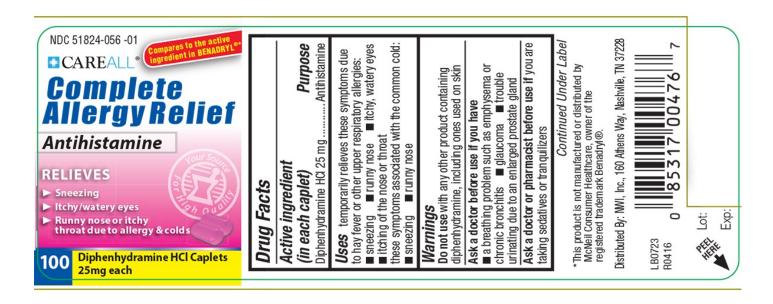
Take every 4 to 6 hours, or as directed by a doctor. Do not take more than 6 times in 24 hours

**Adults and children 12 years of age and older:** 1 to 2 caplets

**Children 6 to 12 years:** 1 caplet **Children under 6:** do not use

# **Inactive Ingredients**

croscarmellose sodium, D C Red 27 aluminum lake, hypromellose, lactose, magnesium stearate, microcystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide



**Drug Facts** (Continued) Inactive ingredients croscarmellose sodium, D&C red #27 aluminum lake, children 6 to under 12 years: 1 caplet children. In case of accidental overdose, beverages ■ alcohol, sedatives, and drowsiness may occur ■ avoid alcoholic hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, do not use if safety seal under cap is contains: 20mg calcium ■ s temperature 20°– 25°C (68°– children under 6 years of age: do not use adults and children 12 years and over: as directed by a doctor do not take more contact a doctor or Poison Control Center (1-800-222-1222) immediately. professional before use. **Keep out of reach o**t occur, especially in children operating machinery 
excitability may When using this product ■ marked Other information than 6 times in 24 hours tranquilizers may increase drowsiness t pregnant or breast-teeding, ask a health **Directions** ■ take every 4 to 6 hours, to 2 caplets be careful when driving a motor vehicle or each caplet store at room

# CAREALL DIPHENHYDRAMINE

diphenhydramine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-056
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	Diphenhydramine Hydro chlo ride	25 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS 185U6K)		
HYDRO XYMETHYL CELLULO SE (UNII: 273FM27VK1)		
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)		
Magnesium Stearate (UNII: 70097M6I30)		
Cellulose, Microcrystalline (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
Silicon Dioxide (UNII: ETJ7Z6XBU4)		
Titanium Dioxide (UNII: 15FIX9 V2JP)		

Product Characteristics			
Color	pink (Bright Pink)	Score	no score
Shape	OVAL (Oval in Shape, sides straight, top and bottom rounded)	Size	11mm
Flavor		Imprint Code	048;D
Contains			

l	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:51824-056-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/28/2016		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/28/2016	

# Labeler - New World Imports, Inc (075372276)

Revised: 10/2019 New World Imports, Inc